REMARKS

Claims 2-8 and 10-22 are pending, of which claims 17, 19, 21 and 22 are independent. The Examiner has withdrawn all previous prior rejections, i.e., those based on U.S. Patent Publication 2001/0004676 to Ouchi, U.S. Patent No. 6,102,887 to Altman, U.S. Patent No. 5,312,361 to Zadini and U.S. Patent No. 6,575,931 to Ponzi. Claims 17-22, 2-4 and 10-12 are now rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,989,197 to Avaltroni ("Avaltroni") and claims 5-8 and 13-16 are now rejected under 35 U.S.C. §103(a) over Avaltroni in view of U.S. Application No. 20020026126 A1 to Bordoff et al. ("Bordoff"). Reconsideration and further examination are respectfully requested in view of the comments below.

I. Drawing Figures.

In the Office Action the Examiner requested that corrected drawings in compliance with 37 C.F.R. 1.121(d) be submitted. Applicant respectfully requests that the drawings as originally filed be replaced with enclosed drawing Figures 1-6 on three sheets.

II. Prior Art Rejections.

Each of independent claims 17, 19, 21 and 22 recite a needle having a solid tip, an internal passage, and a port in fluid communication with the internal passage. The needle is retained at least partially in a catheter lumen prior to deployment is moved at least partially out of the catheter lumen during deployment, and is retracted at least partially back into the catheter lumen afterwards. Neither of the prior art references of record, alone or in combination, teach these features.

1. Pending Independent Claim 17.

Independent Claim 17 recites a medical device for taking a biopsy of material. The medical device includes a catheter having a catheter lumen with a proximal end and a distal end,

a needle, a sheath having a sheath lumen through which the catheter is selectively moved, and a driver for selectively moving the needle with one or more of a predefined force, a predefined acceleration and a predefined velocity to penetrate the material (such as heart tissue). The needle has a solid pointed end for insertion into a body material, an internal passage, and a port in fluid communication with the internal passage for receiving biopsy material. The needle is for selectively moving to (a) extend from the distal end of the catheter lumen to a first position wherein the pointed end and port are inserted into the body material to take the biopsy, and (b) retracted to a second position wherein at least the port is positioned within the catheter lumen.

2. **Pending Independent Claim 19.**

Independent claim 19 recites a medical device for injecting a fluid into a body material. The medical device includes a catheter having a catheter lumen with a proximal end and a distal end, a needle having a side wall, a solid tip, an internal passage, and a port in fluid communication with the internal passage formed in the side wall, the needle for selectively moving (a) to extend from the distal end of the catheter lumen to a first position to inject the fluid into the body material through the port in the side wall, and (b) retract to a second position within the catheter lumen, a sheath having a sheath lumen through which the catheter is selectively moved, and a driver for selectively moving the needle with one or more of a predefined force, a predefined acceleration and a predefined velocity to penetrate the material.

3. **Pending Independent Claim 21.**

Independent claim 21 recites a medical device including a catheter for taking a biopsy of body tissue. The medical device includes a catheter lumen and a needle having an outer surface, a solid pointed end for insertion into body tissue, an internal passage, and a first port in fluid communication with the internal passage open to the outer surface, the needle movable from a

first position to a second position, the first port being positioned in the catheter lumen when the needle is in the first position and being positioned outside of the catheter lumen when the needle is in the second position, wherein when the catheter is used the pointed end and first port are inserted into the body tissue when the needle is moved into the second position in order to collect biopsy material from the body tissue.

4. Pending Independent Claim 19.

Independent claim 22 recites a medical device for injecting a fluid into a material. The medical device includes a catheter having a catheter lumen, and a needle having an outer sidewall, a solid pointed end for insertion into body tissue, a first port open to the outer side wall, and an internal passage in communication with the port, wherein the pointed end and port are inserted into the body tissue and fluid is injected into the body tissue through the port.

5. The Prior Art.

The cited art is not seen to disclose or suggest the limitations of independent claims 17, 19, 21 or 22, and in particular, is not seen to disclose or suggest at least the features of a catheter, a needle having an internal passage and a port in communication with the internal passage, or a needle that extends outward from the catheter and into body material to take a biopsy or make an injection.

U.S. Patent No. 5,989,197A to Avaltroni ("Avaltroni") teaches an automatic biopsy needle supported by a box-shaped case. Abstract; Figs. 1-6. Avaltroni could not be used inside of a blood vessel or formed as part of, or built into, a catheter as is the current device. See independent claims 17, 19, 21 and 22. Further, in the operation of Avaltroni's needle 2, both the stem 3 and cannula 4 are inserted into the organ from which the biopsy is taken. See Col. 6, ll. 30-45 (after the cut sample is enclosed within the cannula the needle must be extracted from the

organ). Inserting both the needle and cannula into an organ would require relatively significant force and potentially cause trauma to the organ. In Applicant's invention, only the needle penetrates the material from which a sample is taken, and the needle has a port that allows tissue to enter. When the needle is removed from the body material it is retracted at least partially into the catheter. The port in the needle may be opened or closed to take a biopsy or the action of the needle moving out of the body material may cut a biopsy of material. Furthermore, the needle of the present invention includes an inner cavity, which is not present in Avaltroni, and injections could not be made utilizing the device taught by Avaltroni. Further, the inner cavity taught by Applicant could be used to extract a biopsy through a catheter lumen without removing the catheter from the body.

U.S. Pending Application No. 2002/0026126 A1 to Burdoff et al. ("Burdoff") does not teach the limitations lacking in Avaltroni.

The remaining claims in this Application are each dependent from one of the aforementioned independent claims and are also believed to be allowable for the reasons stated above.

CONCLUSION

In view of the foregoing, applicant respectfully submits that this Application is in condition for allowance. The Examiner is invited to telephone the undersigned at the telephone number listed below if it would in any way advance prosecution of this case.

By making the amendments herein, Applicant does not concede to a narrower claim scope than originally sought and reserves the right to prosecute different and/or broader claims in any related application.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-3878.

Respectfully submitted,

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David E. Rogers
Reg. No. 38,287

SQUIRE, SANDERS & DEMPSEY L.L.P.
Two Renaissance Square
40 North Central Avenue, Suite 2700
Phoenix, Arizona 85004-4498
(602) 528-4122